REMARKS

Claims

Claims 1, 4, 9, 13–16, 37, 38, 40 and 41 are currently under examination with claims 18, 21, 22, 25, 29–32 and 42 withdrawn from consideration due to restriction/election. Claims 2, 3, 5–8, 10–12, 17, 19, 20, 23, 24, 26–28, 33–36 and 39 are cancelled without prejudice or disclaimer.

Claims 43–47 are added by this paper.

Claim amendments

The amendment of claim 1 is supported by the disclosure contained in, for example, page 12, ¶2; page 8, last paragraph and the disclosure contained in Figs. 10 and 11 of the originally-filed specification. See also, original claim 13 and the disclosure in Example 1.

The amendment of claim 4 is supported by, for example, the disclosure contained in Example 1.1.

Claim 9 has been amended as per conventional US practice and is directed to a combination containing the subcombination (i.e., the immunogenic construct) of the present invention.

New claims 43–45 are supported by the disclosure contained in, for example, the paragraphs bridging page 18, ¶2 to page 20, ¶4 of the originally-filed application. New claims 46–47 are supported by the disclosure contained in, for example, page 45 and Fig. 10 of the originally-filed application. See also, the disclosure contained in the sequence listing.

Applicants respectfully submit that the amendments presented herein do not raise new matter. Entry thereof is earnestly solicited.

Rejoinder

Withdrawn claims 18, 21, 22, 25, 29–32 and 42 are drawn to a method of making/using the compound(s) and/or composition(s) of the instant invention and recite all the elements of Applicants' product claims. "If a product claim is found allowable, process claims that depend from or otherwise require all the limitations of the patentable product may be rejoined." See M.P.E.P. § 806.05.

Rejoinder thereof is therefore respectfully requested.

As to rejoinder of the method claims, the Examiner is cordially invited to revisit the descriptive portion of Applicants' specification directed to such embodiments. See, for example, the disclosure contained in the Examples. Applicants submit that in view of the totality of the disclosure contained in the specification regarding the activity of the claimed molecules, a skilled worker who is

familiar with the techniques of immunotherapy can use routine techniques for making and using the claimed compounds/compositions in a manner recited in the claims. Thus, the statutory requirements under §101 and §112 are duly satisfied. Favorable action is earnestly solicited.

Claim objection

The objection of claim 9 is rendered moot in view of the aforementioned amendments. Withdrawal of the objection is respectfully requested.

Rejection under §112, ¶2

At the outset the rejection of claims 6, 10 and 17 under this section is rendered moot by the cancellation of said claims. No agreement is to be implied. Withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claim 1 under this section for allegedly being indefinite with respect to the "structure" of the immunogenic construct. The claims have been amended to recite immunogenic constructs comprising amino acid sequence(s) of discrete regions of gp41 of HIV-1, which are linked/associated in the claimed conformation via molecules of the present invention (for example, transmembrane envelope protein p15E of another virus or a linker). These structural elements are described in Applicants' own specification. For example, representative examples of linkers are provided in the paragraph bridging pages 28 and 29; representative examples of p15E are provided in Example 1.1 (see, for example, page 46 of the originally-filed specification). Additionally, the gp41 polypeptide sequence of HIV-1 was appreciated in the art before the filing date of the instant application. See, for example, page 8, lines 9–11 and page 9, last paragraph and the disclosure contained in the Examples of Applicants' own specification. Based on this disclosure, a skilled artisan has express knowledge of the metes and bounds of the immunogenic constructs claimed herein. Explicit recitation of polypeptide or polynucleotide sequence(s) is not necessary at all. See also, *Capon v. Eshhar v. Dudas*, (Fed. Cir. 2005) 418 F.3d 1349, 76 U.S.P.Q.2d 1078.

Withdrawal of the rejection is respectfully requested.

Rejection under §112, ¶1 (enablement)

Claim 39, which was rejected under this section, is cancelled without prejudice or disclaimer. The amendment is not to be construed with acquiescence to this or any other ground of rejection. For example, Applicants' specification provides an enabling disclosure for the full scope of the method claims (for example, prophylactic or therapeutic uses), which utilize the elected

product(s)/composition(s). These claims are currently withdrawn from consideration.

Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102(b)

The contention that the subject matter of Applicants' claims 1–4, 7, 33 and 35 is anticipated by Frangione-Beebe (*Vaccine*, vol. 19, 1068-81, 2001) is respectfully traversed.

Under item 12, the Office Action alleges that the reference's disclosure of "HTLV-1 derived immunogenic construct comprising peptide sequences between a TM region and the first helical region, the first and second helical regions and a linker region having sequence identity with a STLV-1 transmembrane protein" anticipates the subject matter of the instant invention. Applicants respectfully disagree. Frangione-Beebe's disclosure of HTLV-1 constructs and STLV-1 derived linker regions fails to anticipate the immunogenic constructs of the present invention. For example, insofar as HTLV-1 is art-recognized to be different from HIV-1, the constructs of the instant application are novel over what is taught by Frangione-Beebe. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §103

The Office Action continues to allege that claims 5, 6, 17 and 34 are unpatentable over the aforementioned Frangione-Beebe in view of Salminen (*Virology*, 1995). Claims 8 and 37 are rejected under the same section as allegedly rendered obvious by Frangione-Beebe in view of Laukkanen (*Biochemistry*, 1994). Claims 13, 14 and 40 are rejected under this section as allegedly unpatentable over the aforementioned Frangione-Beebe in view of Andersson (*Journal of Immunological Methods*, 1999). Claims 15 and 41 are rejected under this section as allegedly unpatentable over the aforementioned Frangione-Beebe in view of Tian (*Immunopharmacology*, 2001). These rejections are respectfully traversed.

At page 10 of the Office Action, it is conceded that Frangione-Beebe "does not teach sequence derived from HIV-1 gp41" but the Examiner proceeds to allege that the structures are taught by Salminen. It is further asserted that "SEQ ID NO: 1 matches amino acids 530-550 of one of the isolates" and was submitted to GenBank under the accession No. AAB60578.1. Applicants respectfully disagree that a combination of the aforementioned references renders the claimed subject matter *prima facie* obvious.

As outlined *supra*, Frangione-Beebe does not teach an immunogenic construct having two sequence units derived from HIV-1 gp41, which are linked with a linker or backbone sequences of p15E of another transmembrane envelope protein (not HIV-1). A combination of the primary

reference with the disclosure in Salminen does also not lead to the present construct. Salminen et al teaches sequences of several full-length HIV-1 clones including the sequence of gp41. However, the secondary reference fails to teach or suggest a construct comprising the domains that are presently recited. More specifically, there is no mention of a construct comprising the transmembrane envelope (TM) protein gp41 of HIV-1 located at the N-terminal part of gp41 (from the middle of the fusion peptide to the beginning of the N-terminal helix, called El), and a domain E2 located in the C-terminal part between the membrane spanning domain and the end of the C-terminal helix. There is also no mention of a p15E polypeptide sequence linking the aforementioned domains. Moreover, even if SEQ ID NO: 1 matches as sequence 538-550 of one of the isolates there is no hint for the construction of an immunogenic construct using two defined sequences of HIV-1 gp4l, namely sequences between the TM region and the C-terminal helix (E2), and between the fusion domain and the N-terminal helix (El) which are preferably derived from as 519 to 564 (El) of the HIV-1 and as 650 to 683 (E2) of the HIV-1. To this end, the Examiner is cordially requested to review the disclosure contained in page 18, second paragraph of the originally-filed specification and the subject matter of new claims. Withdrawal of the rejection is respectfully requested.

With respect to the second rejection under §103(a), the PTO's rationale for *prima facie* case of obviousness is that Frangione-Beebe teaches the claimed constructs and Laukkanen describes a method for preparing peptidyl entities for inclusion in liposomal preparations by attaching a lipid to a portion of a synthetic antibody. However, as asserted *supra*, the primary reference fails to teach or suggest the constructs of the present application and moreover, Laukkanen does not teach liposomes of the selected constructs. A combination of Frangione-Beebe and Laukkanen, at best, would lead a skilled worker to liposomes of ACH-RE3 constructs against HTLV-1.

With respect to the third rejection under §103(a), it is alleged that the subject matter of claims 13, 14 and 40 is rendered obvious by Frangione-Beebe in view of Andersson et al. It is alleged that Andersson describes a method for preparing peptidyl entities for inclusion into ISCOM preparations. However, Andersson et al. does nothing to rectify the limitations of the primary references. A combination of Andersson and Frangione-Beebe, at best, would lead to ISCOM preparations of ACH-RE3 constructs against HTLV-1.

The same is true for the fourth rejection under §103(a), wherein claims 15 and 41 stand rejected as allegedly unpatentable over the aforementioned Frangione-Beebe in view of Tian (*Immunopharmacology*, 2001).

In summary, the cited references, even at their broadest interpretation, fail to *prima facie* render obvious the claims of the instant application. Obviousness requires a suggestion of all the elements in a claim (*CFMT Inc., v Yieldup Int'l Corp.* 349 F.3d 1333, 1342 [68 USPQ2d 1940] (Fed.

Cir. 2003)) and requires a reason that would have prompted [a skilled worker] to combine the elements in the way the claimed new invention does. *Ex parte Alexander* (Decided November 30, 2007; *86 USPQ2d 1120).*

Withdrawal of the rejection is respectfully requested.

Dependent claims

With respect to the other dependent claims at issue, Applicants will not burden the record with a discussion of same since they merely add to the unobviousness of the independent claims; however, Applicants reserve the right to provide rebuttals against the statements in the Office Action *vis-a-vie* the dependent claims, at a later date, if ever necessary.

In the absence of a more pertinent reference, it appears that the application is now in condition for allowance, but if there are any residual issues, the Examiner is courteously invited to telephone Counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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